

Remarks

Upon entry of the foregoing amendment, claims 21-28, 33-40, 42-53, 69-75, and 80-114 are pending in the application. Claims 14, 16, 19-20, 29-32, 41, 54-68, and 76-79 have been canceled without prejudice or disclaimer. Claims 96-114 are new. In addition, claims 21, 37, 38, 45, 46-53, 69, 72-75, 80, 83, 85, 86, 89, 91, 92, and 95 have been amended to more clearly claim embodiments Applicants regard as the invention. Applicants hereby reserve the right to pursue the canceled subject matter in later to be filed continuing applications. The new and amended claims are supported in the specification as filed, therefore, no new matter has been added.

I. The Restriction Requirement

The restriction requirements mailed on June 19, 2002 (Paper No.23) and November 26, 2001 (Paper No.17) have been withdrawn in view of petitions submitted by Applicants on September 19, 2002 and March 27, 2002. *See*, Paper Nos. 20 and 23.

Claims 14, 16, and 19-20 remain withdrawn by the Examiner. As pointed out above, claims 14, 16, and 19 have been canceled without prejudice or disclaimer. Applicants reserve the right to file one or more divisional applications directed to the subject matter of the canceled claims. Applicants thank the Examiner for acknowledging Applicants' timely traversal of the restriction requirement.

II. Rejection of Claims 21-95 Under 35 U.S.C. § 101

The Examiner has rejected claims 21-95 under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility. *See*, Paper No. 28, pages 2-4. In particular, the Examiner asserts the following at page 2, last paragraph to page 3, first paragraph, of the Office Action (emphasis added):

The utility set forth in the specification at p.17, last paragraph, is that of pancreatic cancer diagnosis. This is based on 'An initial Northern blot analysis [that] has shown very high expression in pancreatic cancer cells.' For several reasons this is not a specific or substantial utility. First, it is not known how the level of expression compares to expression in normal noncancerous cells, nor if the expression was analyzed in cell cultures or in cancerous tissue. Markers for cell lines are not necessarily representative of primary cell cultures or in cancerous tissue since it is well known

that cells can undergo changes in expression when cultured for extended passages. Also, a cancer cell is representative of only a single sample (cell lines originate from one patient's cells), which is not enough information to conclude that protein alteration in that cell line is a universal phenomenon in all or most pancreatic cell samples. Second, polynucleotide expression is not necessarily indicative of protein expression. There is no information on altered level of protein (the claimed product) in pancreatic cancer cells.

Therefore, the Examiner asserts that the asserted utilities are neither specific or substantial because (1) the differential levels of expression (cancerous vs. non-cancerous tissue) of the Human Cripin Growth Factor (CGF) is "not known" because expression in cell lines are not necessarily representative of primary cell cultures or cancerous tissue; and (2) polynucleotide expression is not necessarily indicative of protein expression.

Applicants respectfully disagree and traverse.

Preliminarily, Applicants respectfully point out that, according to the M.P.E.P., the burden is on the Examiner to establish that it is more likely than not that a person of ordinary skill in the art would not consider the utility asserted by Applicants to be specific, substantial, and credible. *See*, M.P.E.P. § 2107 at 2100-30. Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *Id.* at 2100-40. The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the Applicants' assertion of utility. *See id.*; *See also In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, the Examiner has not met the burden that is necessary to establish and maintain a rejection of claims 21-95 for lack of utility under 35 U.S.C. § 101.

Further, Applicants respectfully point out that M.P.E.P. § 2107.01 reads as follows:

A 'specific utility' is specific to the subject matter claimed. This is in contrast with a general utility that would be applicable to a broad class of the invention. [Where] applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition [this is] sufficient to identify a specific utility for the invention.

M.P.E.P. § 2107.01 at 2100-32. In addition, M.P.E.P. § 2107.01 reads:

A substantial utility defines a 'real world' use...Any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient.

See, M.P.E.P. § 2107.01 at 2100-33

In order to find that an asserted utility is not specific or substantial, the burden is on the Examiner to make a *prima facie* showing that it is more likely than not that a person of ordinary skill in the art would not consider any utility asserted by the Applicant to be specific or substantial. *See*, M.P.E.P. § 2107.02(IV); Utility Examination Guidelines, 66 FR 1092, January 5, 2001 at 1098, col. 3 (emphasis added). Such a *prima facie* showing must contain (1) an explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established; (2) support for factual finding relied upon in reaching this conclusion; and (3) evaluation of all relevant evidence of record, including utilities taught in the closest prior art. *See id.*

In the present case, the Examiner has simply stated that "markers for cell lines are not necessarily representative of primary cell cultures or in cancerous tissue" and "polynucleotide expression is not necessarily indicative of protein expression." *See*, Paper No.28, page 2, last paragraph to page 3, first paragraph. Importantly, no evidence is provided as to how the Examiner reached this conclusion nor has the examiner provided reasoning or evidence as to why the skilled artisan would more likely than not consider any utility asserted by the Applicant to be specific or substantial based on the entire teachings in the specification. Further, Applicants respectfully point out that whether or not something is necessarily indicative of a particular result is not the proper standard upon which to conclude an asserted utility is not specific or substantial. Thus, the Examiner has not met the burden required to maintain a utility rejection under 35 U.S.C. § 101.

Notwithstanding the above discussion, Applicants contend that, contrary to the Examiner's allegations, Applicants have set forth in the specification several statements that clearly provide the specific, substantial, and credible asserted utility that the Examiner contends is lacking. For example, Applicants disclose that the gene, which encodes the polypeptide of the invention (SEQ ID NO: 2), is overexpressed by pancreatic cancer cells (not cell lines) and that detection of an excessive amount of CGF protein allows a pancreatic cancer diagnosis. *See*,

specification at page 2, line 7-9 and page 17, lines 31-33. In addition, the specification teaches that the CGF of the invention is homologous to cripto growth factor, a well-known tumor marker, which is overexpressed in pancreatic and colon cancers (not cell lines). *See*, page 2, lines 12-16; and page 4, lines 6-8 and 17-18; and Figure 2. Further, Applicants discloses *in vitro* data supporting the assertion that the polypeptide of the invention would be useful as a diagnostic marker of pancreatic cancer. For instance, Northern blot analysis shows that the mRNA expressing the CGF of the invention is highly expressed in pancreatic cancer cells (not cell lines). *See*, page 4, lines 29-30. In fact, the polynucleotides encoding CGF were derived from a pancreatic cancer tissue cDNA library. *See*, specification at page 4, lines 15-17. Therefore, based in part on both tissue expression and homology to a known pancreatic cancer diagnostic marker, Applicants have asserted that detection of overexpression of the CGF polypeptide of the invention would facilitate pancreatic cancer diagnosis.

This asserted utility is specific and substantial. First, the disclosed use of the CGF polypeptides of the invention is not generally applicable to all proteins. For instance, all proteins are not useful in providing markers for differential identification of pancreatic cancer. Second, the use of the claimed polypeptides to diagnose pancreatic cancer is certainly a "real world" use and, therefore, is a substantial utility.

Moreover, while the Examiner has neither explicitly discussed the credibility of the asserted utilities nor provided Applicants evidence or reasoning undermining the credibility of the asserted utilities, Applicants submit that, in light of the teachings of the specification and in view of what was known at the time the invention was filed, one of ordinary skill in the art would have found the Applicants' asserted utility to be more likely than not true, and therefore, the Applicants' asserted utility is credible. As discussed *supra*, in assessing the credibility of the asserted utilities, the burden is on the Examiner to establish why it is more likely than not that one of ordinary skill in the art would doubt (*i.e.*, "question") the truth of the statement of utility. M.P.E.P. § 2107 at 2100-30 and 2100-40. Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *Id.* The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the Applicants' assertion of utility. *See Id.*; *see also, In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995).

In *In re Brana*, the inventors asserted that the disclosed novel compounds were useful to treat cancer, *i.e.*, they had antitumor properties. See, *In re Brana* 51 F.3d 1560 (Fed. Cir. 1995); *see also* specification of Patent No. 5,552,544. In support of their assertion, the inventors disclosed that their novel compounds 1) were structurally similar to known compounds having antitumor activity; and 2) showed *in vitro* activity against human tumor cells. The Federal Circuit held that the assertions of utility disclosed in the Brana specification were sufficient and that

FDA approval is not a prerequisite for finding a compound useful within the meaning of the patent laws...Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation for further research and development.

Id at 1563. Moreover, as stated in the M.P.E.P. § 2107.01 (III) at 2100-34, “[c]ourts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides ‘an immediate benefit’ and thus satisfies the utility requirement.”

As discussed above, Applicants have disclosed a novel polypeptide that is structurally related to cripto growth factor, a well-known cancer marker, which is overexpressed in pancreatic and colon cancer cells. In addition, Applicants have asserted that detection of overexpression of the CGF polypeptide of the invention would facilitate pancreatic cancer diagnosis. Further, Applicants have provided *in vitro* activity which supports the asserted diagnostic use. Thus, one skilled in the art would more likely than not believe the truth of the statement of utility.

Applicants submit that, for the reasons stated above, the utility asserted in the specification for the Human Criptin Growth Factor is indeed *specific, substantial and credible*. Accordingly, Applicants respectfully submit that the rejection of claims 24-63 under 35 U.S.C. § 101 has been obviated. Applicants respectfully request that the rejection of claims 21-95 under 35 U.S.C. § 101 be reconsidered and withdrawn.

For the reasons discussed above in response to the rejection under 35 U.S.C. § 101, the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner “should not impose a 35 U.S.C. § 112, first paragraph, rejection grounded on a ‘lack of utility’ basis unless a 35 U.S.C. § 101 rejection is proper.” M.P.E.P. § 2107 (IV) at 2100-36. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. § 101, the rejections under 35 U.S.C. § 112, first paragraph, based on the alleged lack of utility of the claimed

invention, should be withdrawn. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

III. Written Description Rejections Under 35 U.S.C. § 112

The Examiner has rejected claims 21, 29-33, 35-38, and 41-83 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *See*, Paper No. 28, pages 4-7.

In particular the Examiner asserts that claims reciting fragments 68-223, 129-207, and 173-207 of SEQ ID NO:2 (*i.e.*, claims 21, 46, 73, and claims dependent thereon [*i.e.*, claims 29-31, 54-56, and 65-67]) are new matter in view of the amendments to SEQ ID NO:2 set forth in the preliminary amendment dated December 8, 1999. *See*, Paper No.28, pages 5-6. In addition, the Examiner asserts that claims drawn to fragments of SEQ ID NO:2 that stimulate cell growth (*i.e.*, claims 21, 32, 38, 41, 46, 57, 68, 73, 76, and 79) are not adequately supported by the specification.

Applicants respectfully disagree, but in the interest of facilitating prosecution, Applicants have amended independent claims 21, 38, 46, and 73 and canceled claims 29-32, 41, 54-57, 65-68, 76, and 79. Therefore, Applicants respectfully request that the rejection of claims 21, 29-33, 35-38, and 41-83 under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

IV. Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 37, 45, 47-69, 72, 74-80, 83, 85, 89, 91, and 95 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. *See*, Paper No.28, pages 7-8.

A. The Examiner asserts at page 7 of the Office Action:

Claims such as 37 are rejected under 35 U.S.C. § 112, second paragraph as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. *See* MPEP § 2172.01. The omitted elements are: the means by which the protein can be produced. There is nothing to indicate the host cell anything by which it can produce the protein, for example, a

nucleic acid encoding the protein. It is not clear whether the host cell has been transformed with a nucleic acid that encodes the desired protein, or alternatively whether the host cell naturally makes the protein (and its being a 'host' is irrelevant to the method). Further, in step (b), it is unclear if 'the protein' recovered is said isolated protein of claim 21 or if it is another protein in/from the cell. Claims 45, 72, 83, 89, and 95 are similarly indefinite.

Applicants respectfully disagree, but in the interest of facilitating prosecution, Applicants have amended claims 37, 45, 72, 83, 89, and 95, thereby obviating the rejection. Therefore, Applicants respectfully request that the rejection of claims 37, 45, 72, 83, 89, and 95 under 35 U.S.C. § 112, second paragraph, be withdrawn.

B. The Examiner further asserts that claims which recite "the isolated protein of claim X which further comprises" (*i.e.*, claims 47-68 and 74-79) are indefinite because it is allegedly unclear "whether applicants intend that there be a second sequence meeting the further limitation fused to the first, or whether applicants actually intend the dependent claim to further limit the first sequence." *See*, Paper No.28, pages 7-8.

Applicants respectfully disagree, but in the interest of facilitating prosecution, Applicants have amended claims 47-53 and 74-75; and canceled claims 58-68 and 77-78 (the subject matter being replaced by new claims 96-103 and 108-110, respectively), thereby obviating the rejection. Claims 54-57, 76, and 79 were also canceled as mentioned above. Therefore, Applicants respectfully request that the rejection of claims 47-68 and 74-79 under 35 U.S.C. § 112, second paragraph, be withdrawn.

C. The Examiner further asserts that claims 69, 80, 85, and 91 are indefinite because the claims, from which they depend, "uses the term 'amino acid sequence' twice, to refer both to the claimed subject matter and that which it is compared." *See*, Paper No.28, page 8.

Preliminarily, Applicants respectfully point out, based on the Examiner's reasoning as to why claims 69 and 80 are rejected, it seems the Examiner meant to include claims 86 and 92 in the rejection rather than claims 85 and 90.

Applicants respectfully disagree with the Examiner's rejection, but in the interest of facilitating prosecution, Applicants have amended claims 69, 80, 86, and 92, thereby obviating the rejection.

D. The Examiner further asserts that claims 85 and 91 are indefinite because it is not clear whether applicants intend to claim separate fragments or fragments at least 50 amino acids long. *See*, Paper No.28, page 8, first full paragraph.

Applicants respectfully disagree with the Examiner's rejection, but in the interest of facilitating prosecution, Applicants have amended claims 85 and 91, thereby obviating the rejection.

In view of the above, Applicants respectfully request that the rejection of claims 37, 45, 47-69, 72, 74-80, 83, 85, 89, 91 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Conclusion

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Meissner et al.

Application Number: 09/393,023

Group Art Unit: 1646

Filed: September 9, 1999

Examiner: Spector, L.

Title: Human Cripin Growth Factor

Attny. Docket No.: PF200D1

VERSION WITH MARKINGS
TO SHOW CHANGES MADE

In the Claims:

Claims 14, 16, 19-20, 29-32, 41, 54-68, and 76-79 have been canceled.

The claims have been amended as follows:

21. (Once Amended) An isolated protein comprising a polypeptide having an amino acid sequence selected from the group consisting of:

- (a) amino acid residues 1 to 223 of SEQ ID NO:2;
- (b) amino acid residues 1 to 173 of SEQ ID NO:2;
- (c) amino acid residues 24 to 223 of SEQ ID NO:2;
- (d) amino acid residues 24 to 67 of SEQ ID NO:2;
- (e) amino acid residues 24 to 173 of SEQ ID NO:2;
- (f) amino acid residues 45 to 128 of SEQ ID NO:2; and
- (g) amino acid residues 68 to 173 of SEQ ID NO:2 ;
- ~~(h) amino acid residues 68 to 223 of SEQ ID NO:2;~~
- ~~(i) amino acid residues 129 to 207 of SEQ ID NO:2;~~
- ~~(j) amino acid residues 174 to 223 of SEQ ID NO:2; and~~
- ~~(k) a polypeptide fragment of amino acids 1 to 223 of SEQ ID NO:2 wherein said polypeptide fragment stimulates cell growth.~~

37. (Once Amended) A protein produced by a method comprising:

- (a) expressing a nucleic acid encoding ~~culturing a host cell under conditions suitable to produce~~ the isolated protein of claim 21 in a host cell transformed with said nucleic acid; and

(b) recovering the protein produced by the method.

38. (Once Amended) An isolated protein comprising an amino acid sequence selected from the group consisting of:

(a) the complete polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142; and

(b) the mature form of the polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142; and

~~(c) a polypeptide fragment of the complete polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142 wherein said polypeptide fragment stimulates cell growth.~~

45. (Once Amended) A protein produced by a method comprising:

(a) expressing a nucleic acid encoding ~~culturing a host cell under conditions suitable to produce~~ the isolated protein of claim 38 in a host cell transformed with said nucleic acid; and

(b) recovering the protein produced by the method.

46. (Once Amended) An isolated protein comprising ~~an~~ a first amino acid sequence 90% or more identical to ~~an~~ a second amino acid sequence selected from the group consisting of:

(a) amino acid residues 1 to 223 of SEQ ID NO:2;

(b) amino acid residues 1 to 173 of SEQ ID NO:2;

(c) amino acid residues 24 to 223 of SEQ ID NO:2;

(d) amino acid residues 24 to 67 of SEQ ID NO:2;

(e) amino acid residues 24 to 173 of SEQ ID NO:2;

(f) amino acid residues 45 to 128 of SEQ ID NO:2; and

(g) amino acid residues 68 to 173 of SEQ ID NO:2 ;

~~(h) amino acid residues 68 to 223 of SEQ ID NO:2;~~

~~(i) amino acid residues 129 to 207 of SEQ ID NO:2;~~

~~(j) amino acid residues 174 to 223 of SEQ ID NO:2; and~~

~~(k) a polypeptide fragment of amino acids 1 to 223 of SEQ ID NO:2 wherein said polypeptide fragment stimulates cell growth.~~

47. (Once Amended) The isolated protein of claim 46, wherein said second amino acid sequence is (a) ~~which further comprises an amino acid sequence 90% or more identical to amino acid residues 1 to 223 of SEQ ID NO:2.~~

48. (Once Amended) The isolated protein of claim 46, wherein said second amino acid sequence is (b) ~~which further comprises an amino acid sequence 90% or more identical to amino acid residues 1 to 173 of SEQ ID NO:2.~~

49. (Once Amended) The isolated polypeptide of claim 46, wherein said second amino acid sequence is (c) ~~which further comprises an amino acid sequence 90% or more identical to amino acid residues 24 to 223 of SEQ ID NO:2.~~

50. (Once Amended) The isolated protein of claim 46, wherein said second amino acid sequence is (d) ~~which further comprises an amino acid sequence 90% or more identical to amino acid residues 24 to 67 of SEQ ID NO:2.~~

51. (Once Amended) The isolated protein of claim 46, wherein said second amino acid sequence is (e) ~~which further comprises an amino acid sequence 90% or more identical to amino acid residues 24 to 173 of SEQ ID NO:2.~~

52. (Once Amended) The isolated protein of claim 46, wherein said second amino acid sequence is (f) ~~which further comprises an amino acid sequence 90% or more identical to amino acid residues 45 to 128 of SEQ ID NO:2.~~

53. (Once Amended) The isolated protein of claim 46, wherein said second amino acid sequence is (g) ~~which further comprises an amino acid sequence 90% or more identical to amino acid residues 68 to 173 of SEQ ID NO:2.~~

69. (Once Amended) The isolated protein of claim 46 wherein ~~the amino acid sequence~~ said isolated protein further comprises a heterologous polypeptide.

72. (Once Amended) A protein produced by a method comprising:

- (a) expressing a nucleic acid encoding ~~culturing a host cell under conditions suitable to produce~~ the isolated protein of claim 46 in a host cell transformed

with said nucleic acid; and

(b) recovering the protein produced by the method.

73. (Once Amended) An isolated protein comprising ~~an~~ a first amino acid sequence 90% or more identical to ~~an~~ a second amino acid sequence selected from the group consisting of:

(a) the complete polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142; and

(b) the mature form of the polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142 ~~;~~ and

~~(c) a polypeptide fragment of the complete polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142 wherein said polypeptide fragment stimulates cell growth.~~

74. (Once Amended) The isolated protein of claim 73 ~~which further comprises an amino acid sequence 90% or more identical to the amino acid sequence of the complete polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142,~~ wherein said second amino acid sequence is (a).

75. (Once Amended) The isolated protein of claim 73 ~~which further comprises an amino acid sequence 90% or more identical to the amino acid sequence of the complete polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142,~~ wherein said second amino acid sequence is (b).

80. (Once Amended) The isolated protein of claim 73 wherein ~~the amino acid sequence~~ said isolated protein further comprises a heterologous polypeptide.

83. (Once Amended) A protein produced by a method comprising:

(a) expressing a nucleic acid encoding ~~culturing a host cell under conditions suitable to produce~~ the isolated protein of claim 73 in a host cell transformed with said nucleic acid; and

(b) recovering the protein produced by the method.

85. (Once Amended) The isolated protein of claim 84 ~~further~~ comprising at least 50 contiguous amino acids of SEQ ID NO:2.

86. (Once Amended) The isolated protein of claim 84 wherein ~~the amino acid sequence~~ said isolated protein further comprises a heterologous polypeptide.

89. (Once Amended) A protein produced by a method comprising:
(a) expressing a nucleic acid encoding ~~culturing a host cell under conditions suitable to produce~~ the isolated protein of claim 84 in a host cell transformed with said nucleic acid; and
(b) recovering the protein produced by the method.

91. (Once Amended) The isolated protein of claim 90 ~~further~~ comprising at least 50 contiguous amino acids of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 97142.

92. (Once Amended) The isolated protein of claim 90 wherein ~~the amino acid sequence~~ said isolated protein further comprises a heterologous polypeptide.

95. (Once Amended) A protein produced by a method comprising:
(a) expressing a nucleic acid encoding ~~culturing a host cell under conditions suitable to produce~~ the isolated protein of claim 90 in a host cell transformed with said nucleic acid; and
(b) recovering the protein produced by the method.

The following new claims have been added:

96. (New) An isolated protein comprising a first amino acid sequence 95% or more identical to a second amino acid sequence selected from the group consisting of:

- (d) amino acid residues 1 to 223 of SEQ ID NO:2;
- (e) amino acid residues 1 to 173 of SEQ ID NO:2;
- (f) amino acid residues 24 to 223 of SEQ ID NO:2;
- (d) amino acid residues 24 to 67 of SEQ ID NO:2;
- (e) amino acid residues 24 to 173 of SEQ ID NO:2;

- (f) amino acid residues 45 to 128 of SEQ ID NO:2; and
(g) amino acid residues 68 to 173 of SEQ ID NO:2.

97. (New) The isolated protein of claim 96, wherein said second amino acid sequence is (a).

98. (New) The isolated protein of claim 96, wherein said second amino acid sequence is (b).

99. (New) The isolated protein of claim 96, wherein said second amino acid sequence is (c).

100. (New) The isolated protein of claim 96, wherein said second amino acid sequence is (d).

101. (New) The isolated protein of claim 96, wherein said second amino acid sequence is (e).

102. (New) The isolated protein of claim 96, wherein said second amino acid sequence is (f).

103. (New) The isolated protein of claim 96, wherein said second amino acid sequence is (g).

104. (New) The isolated protein of claim 96, wherein said isolated protein further comprises a heterologous polypeptide.

105. (New) The isolated protein of claim 96, wherein said isolated protein is glycosylated.

106. (New) A composition comprising the isolated protein of claim 96 and a pharmaceutically acceptable carrier.

107. (Once Amended) A protein produced by a method comprising:

- (a) expressing a nucleic acid encoding the isolated protein of claim 96 in a host cell transformed with said nucleic acid; and
- (b) recovering the protein produced by the method.

108. (New) An isolated protein comprising a first amino acid sequence 95% or more identical to a second amino acid sequence selected from the group consisting of:

- (a) the complete polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142; and
- (b) the mature form of the polypeptide encoded by the cDNA clone contained in ATCC Deposit No. 97142.

109. (New) The isolated protein of claim 108, wherein said second amino acid sequence is (a).

110. (New) The isolated protein of claim 108, wherein said second amino acid sequence is (b).

111. (New) The isolated protein of claim 108, wherein said isolated protein further comprises a heterologous polypeptide.

112. (New) The isolated protein of claim 108, wherein said isolated protein is glycosylated.

113. (New) A composition comprising the isolated protein of claim 108 and a pharmaceutically acceptable carrier.

114. (New) A protein produced by a method comprising:

- (a) expressing a nucleic acid encoding the isolated protein of claim 108 in a host cell transformed with said nucleic acid; and
- (b) recovering the protein produced by the method.